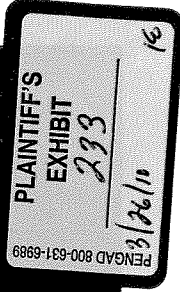


# **EXHIBIT 233**

# CHRONOLOGY OF ACTAVIS TOTOWA (formerly AMIDE) REGULATORY ISSUES



# CHRONOLOGY OF AMIDE REGULATORY ISSUES

November 29 – December 08, 1999 – 483  
Report

December 23, 1999 – 483 Company Response

# CHRONOLOGY OF AMIDE REGULATORY ISSUES

- October 29 - November 29, 2001 – 483 Report
- December 10, 2001 – 483 Company Response
- June 10, 2002 – Letter removing Amide from  
Consent Decree of Injunction
- October 11, 2002 – Warning Letter

# CHRONOLOGY OF AMIDE REGULATORY ISSUES

- April 14-25, 2003 – 483 Report
- May 05, 2003 – 483 Company Response
- August 12-21, 2003 – 483 Report
- September 19, 2003 – 483 Company Response
- November 15 – December 01, 2004 –  
– 483 Report
- December 16, 2004 – 483 Company Response



# CHRONOLOGY OF AMIDE REGULATORY ISSUES

February 28, 2006 – 483 Report Company  
Response

May 2, 2006 – Amide issues *Annual Periodic Adverse Drug Experience Report for Digoxin Tablets, USP 0.125mg and 0.25mg; ANDA 40-282*

July 10 – August 10, 2006 – 483 Report  
August 29, 2006 – 483 Report Company  
Response

# CHRONOLOGY OF AMIDE REGULATORY ISSUES

- August 15, 2006 – Warning Letter for January/February 2006 inspection
- September 11, 2006- Response to Warning Letter (addressing Marketed Products)
- October 11, 2006 – 483 Report
- November 06, 2006 – 483 Company Response

# CHRONOLOGY OF AMIDE REGULATORY ISSUES

## Ongoing Issues:

- Inability to retrieve documents
- Not following 72 hour notification process required by Supply Agreement
- Consistent issues in repeated inspections



# CHRONOLOGY OF AMIDE REGULATORY ISSUES

## Current QA Needs:

- ☐ Quality Agreement
- ☐ Confirmation of Completion of Regulatory Commitments

Chuck Koon/MGW/MYLAN

05/05/2008 08:53 AM

To Patricia Latzo/MGW/MYLAN@MYLAN

cc

bcc

Subject Actavis/Digitek Regulatory Issues

Trish,  
Here is the powerpoint presentation for Actavis (Amide) that I presented to the Outsourced Product Meeting in January 2007.  
Let me know if you need anything else.  
Thanks,  
Chuck



CHRONOLOGY OF AMIDE REGULATORY ISSUES.ppt